

NEWS RELEASE



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## Pervasis Therapeutics Successfully Completes Enrollment for Vascugel™ Phase II Clinical Trials

*Pioneer in regenerative cell-based therapies and devices rapidly fulfills patient recruitment goals for its Multi Arm Phase II Clinical Trials of the first cell-based treatment for damaged arteries*

Cambridge, Massachusetts - August 13, 2007 - Pervasis Therapeutics, Inc., a pioneer in regenerative cell-based therapies and devices, today announced that it has successfully completed patient recruitment for its two Phase II clinical trials involving the company's first product, Vascugel™.

The Phase II clinical studies are to evaluate the continued safety of Vascugel™ as well as its efficacy in the maintenance of vascular patency after creation of arteriovenous (AV) access grafts and AV fistulae in patients undergoing dialysis for treatment of end-stage renal disease (ESRD). Recent Phase I results for Vascugel™ demonstrated that all primary endpoints of the study were achieved, with no significant safety issues.

Vascugel™ is a novel allogeneic cell therapy product that may restore natural repair and regeneration pathways in traumatized human vasculature. The biological activity of Vascugel™ enables its application to a broad array of vascular procedures, in which poor medical outcomes are determined by intimal hyperplasia, stenosis and loss of patency at or near the site of intervention.

Steve Bollinger, President of Pervasis Therapeutics, said, "Vascugel™'s two Phase II studies have gotten off to a promising start, as we have completed full patient enrollment in a very short time. We are certain these study arms hold strong potential for creating innovative and highly useful metrics and methods for evaluating the efficacy of this unique class of therapies for vascular disease."

He added, "We are confident of seeing intriguing results in terms of further safety and efficacy as the two Vascugel™ trials progress. We will examine the possibility of expanding its projected use for further indications in peripheral and coronary vascular diseases later this year."

Dr. Marc Glickman, Vascular & Transplant Specialists, Norfolk, Virginia, and President-Elect of the Vascular Access Society of the Americas (VASA) said, "Vascugel™ has shown great promise in its initial target population in the Phase I Clinical Trial to date, and we anticipate strong findings as it progresses through the current Multi Arm Phase II AVF and AVG studies throughout 2007. The promise of utilizing human endothelial cells to maintain vascular patency encompasses a growing range of potential indications, and we look forward to validating Vascugel™'s continued safety with this clinical trial."

Added Dr. John Ross, Chief of Surgery, Bamberg County Hospital, Bamberg, South Carolina, "The technology we are studying today potentially holds the keys to a better quality surgical intervention, be it invasive or minimally invasive, and shows early promise as a truly revolutionary platform technology."

Pervasis is conducting its "V-HEALTH" (Vascular intimal Hyperplasia: Extending Arterial and venous patency, Limiting vascular Trauma, and inhibiting Hyperplasia while re-establishing vascular health) Phase II Multi Arm clinical trials in patients with ESRD that require a permanent AV access for hemodialysis. Vascugel™ is the first therapy being developed to simultaneously improve outcomes for the two primary forms of surgical arteriovenous access, namely, AV grafts and AV fistulas. There are over 300,000 patients undergoing hemodialysis in the United States today, with an estimated annual growth rate of nearly 5% for new AV graft and AV fistula procedures performed each year.

### **About Vascugel™**

Vascugel™ is a novel and unique allogeneic cell therapy product under investigation for enhancing repair and preventing clinical failure of the vasculature after vascular surgery and intervention. Vascugel™ builds on concepts of tissue engineering to enable implantation of allogeneic endothelial cells in a controlled state. When wrapped around an injured blood vessel, Vascugel™ endothelial cells provide growth regulatory compounds to the

underlying blood vessel, which may promote a natural healing process and prevent excessive scar tissue formation, inflammation and thrombosis.

### **About Vascular Access Failure**

Vascular access failure is a major complication in providing care to patients on hemodialysis to treat end-stage renal disease (ESRD). The prevalent ESRD population in the U.S. is expected to grow to 1.3 million by 2030. According to Medicare reports, total ESRD costs reached \$20.1 billion in 2004 - with total ESRD costs reaching \$32.5 billion from all sources.

According to the United States Renal Data System (USRDS), the number of ESRD patients requiring hemodialysis in 2004 reached over 300,000. According to Medicare data, vascular access complications account for up to 25 percent of all hemodialysis patient admissions, leading to about \$1.5 billion in annual Medicare expenditures.

### **About Pervasis Therapeutics, Inc.**

Pervasis Therapeutics, Inc. is a pioneer in regenerative cell-based therapies and devices. Pervasis is currently developing technologies to restore natural blood flow to critical organs. The company's flagship product, Vascugel™, is a cell-based therapeutic gel currently being developed to help reverse acute vascular injury.

Pervasis' investors include Polaris Venture Partners, Flagship Ventures and Highland Capital Partners. The company was founded by Elazer Edelman, Robert Langer, Joseph Vacanti, and Helen Nugent.

For more information, please visit [www.pervasistx.com](http://www.pervasistx.com).

*This news release contains certain forward-looking statements that involve risks and uncertainties. Such statements are only predictions and the company's actual results may differ materially from those anticipated in these forward-looking statements. Factors that may cause such differences include the timing of clinical trials, the risk that products that appeared promising in early research and clinical trials do not demonstrate safety or efficacy in clinical trials and the risk that the company will not obtain approval to market its products.*